We claim:

1. Ultralente-like crystals having a uni-modal particle size distribution comprising:

a) insulin, an insulin analog, a derivatized insulin, or a derivatized insulin analog; and

b) a divalent metal cation;

characterized in that the volume mean spherical equivalent diameter of the crystals is from 1 micron to 5 microns.

2. Crystals according to Claim 1, wherein the divalent metal cation is zinc.

3. Crystals according to Claim 2 wherein zinc is present at about 0.3 to about 2.0 mole per mole of insulin, insulin analog, derivatized insulin or derivatized insulin analog.

4. Crystals according to any one of Claims 1 - 3, wherein the volume mean spherical equivalent diameter is from 1.5 microns to 4.5 microns.

5. Crystals according to Claim 4 wherein the volume mean spherical equivalent diameter is from 2 microns to 4 microns.

6. A process for preparing crystals according to any one of Claims 1 - 5, comprising;

a) preparing a crystallization solution comprising insulin, an insulin analog, a derivatized insulin or a derivatized insulin analog, a buffer, a salt and a divalent cation;

b) combining the crystallization solution of step a) with a nucleating seed suspension; and

c) allowing time for the seeded crystallization solution of step b) to generate the crystals according to any one of Claims 1 - 5.

7. The process of Claim 6 wherein the nucleating seed suspension comprises insulin or a derivatized insulin.

8. The process of Claim 6 wherein the volume of nucleating seed suspension is equivalent to about 5 to about 25 percent of the volume of the seeded crystallization solution.

9. The process of Claim 8 wherein the volume of nucleating seed suspension is equivalent to about 8 to about 20 percent of the volume of the seeded crystallization solution.

10. The process of Claim 9 wherein the volume of nucleating seed suspension is equivalent to about 10 to about 15 percent of the volume of the seeded crystallization solution.

11. The process of Claim 6 wherein the seeded crystallization solution has a protein concentration of about 0.5 to about 20 mg/ml.

12. The process of Claim 11 wherein the seeded crystallization solution has a protein concentration of about 1 to about 10 mg/ml.

13. The process of Claim 12 wherein the seeded crystallization solution has a protein concentration of about 2 to about 4 mg/ml.

14. The process of Claim 6 wherein the divalent metal cation is zinc.

15.The process of Claim 6 wherein the crystallization proceeds for 1 to about 48 hours.

16. The process of Claim 15 wherein the crystallization process proceeds for 2 to about 30 hours.

17. The process of Claim 16 wherein the crystallization process proceeds for 3 to about 25 hours.

18.The process of Claim 6 wherein the buffer is sodium acetate and the salt is sodium chloride.

19.The process of Claim 8 wherein the crystallization solution further comprises citrate.

20. A pharmaceutical composition for administration by inhalation by mouth comprising the crystals according to of any one of Claims 1 - 5.

21. The pharmaceutical composition of Claim 20 further comprising a carrier, an additive, an excipient, or an aqueous solvent.

22. The pharmaceutical composition of Claim 21 wherein the crystals are in the form of a dry powder.

23. The pharmaceutical composition of Claim 21 further comprising a non-crystalline form of insulin, an insulin analog, derivatized insulin or derivatized insulin analog.

24. Use of the crystals according to of any one of Claims 1 - 5 to prepare a medicament for the treatment of diabetes or hyperglycemia by mouth.

25. A method of using the crystals according to any one of the Claims 1 - 5 to treat diabetes or hyperglycemia using a device to administer the crystals by inhalation via the mouth to a patient in need of such treatment.

26. A method of treating diabetes comprising administering the pharmaceutical composition according to

any one of the Claims 20 - 23 to a patient in need thereof to regulate blood glucose levels in the patient.

27. The method of treating diabetes according to Claim 26 wherein the pharmaceutical composition is administered once a day to the patient.